Claims

1. A pharmaceutical composition comprising
   (i) a biologically active agent;
   (ii) an adjuvant chemical which increases the effect of the biologically active agent, said chemical selected from one or more of:
      A) a polyamino acid,
      B) a water soluble vitamin or vitamin derivative,
      C) positively charged cationic pluronics,
      D) a clathrate,
      E) a complexing agent,
      F) cetrimides;
      G) an S-layer protein
      H) Methyl-glucamine; and
   (iii) a pharmaceutically acceptable carrier or diluent, subject to the following provisos

a) when the chemical (ii) above is selected from D) or E), the biologically active agent is an agent which is capable of generating a protective immune response in an animal to which it is administered;

b) when the chemical (ii) above is selected from A) and the biologically active agent is an agent which is capable of generating a protective immune response in an animal to which it is administered, the composition is for administration to a mucosal surface,

c) when the chemical (ii) above is selected from C) and the biologically active agent is an agent which is capable of generating a protective immune response in an animal to which it is administered, the composition does not contain a polyacrylic acid, and

d) where the chemical (ii) above is selected from G) and the biologically active agent is an agent which is capable of generating a protective immune r sponse in an animal to which it is administered, the carrier or diluent of (iii) is a microsphere or liposome.

2. A composition according to claim 1 wherein biologically active agent is an agent that is capable of generating a protective immune response in an animal to which it is administered.

3. A composition according to claim 1 or claim 2 wherein the said adjuvant chemical can act as an immunostimulant.

4. A composition according to any one of the preceding claims wherein the said adjuvant chemical is selected from one or more of;

A) poly-ornithine, for example of molecular weight from 5 to 150kDa;

B) water soluble vitamins or vitamin derivatives such as vitamin E TPGS (d-alpha tocophenyl polyethylene glycol 1000 succinate),

C) cationic pluronics which are block copolymers or surfactants which are positively charged, in particular with NH_2^+ groups

D) complexing agents which form complexes with fatty acids such as deoxycholic acid, or

E) cyclodextrins and their derivatives such as dimethyl β cyclodextrin.

5. A composition according to any one of the preceding claims wherein the carrier comprises a particle.

6. A composition according to claim 5 wherein the particle is a microsphere or liposome.

7. A composition according to claim 6 which comprises a microsphere.

8. A composition according to claim 7 wherein the microsphere is prepared using a high molecular weight polymer.

9. A composition according to claim 8 wherein the polymer has a molecular weight of 100kDa or more.

10. A composition according to any one of claims 7 to 9 wherein the microsphere comprises poly-(L-lactide).

11. A composition according to any one of the preceding claims wherein the ratio of the chemical (ii) to the carrier is from 99:1 to 9:1 w/w.

12. A composition according to any one of the preceding claims which is adapted for administration to a mucosal surface or is suitable for parenteral administration.

13. A composition according to claim 2 which further comprises a further adjuvant.

14. A method of producing a prophylactic or therapeutic vaccine, which method comprises encapsulating a polypeptide which is capable of producing a protective immune response in a first polymeric material which has a high molecular weight, in the presence of a second polymeric material which increases the biological effect of the composition.

15. A method of protecting a mammal against infection, which method comprises administration of a composition according to any one of claims 1 to 13 to a mammal.

16. A method according to claim 15 wherein the composition is applied to a mucosal surface.

17. A method according to claim 16 wherein the mucosal surface comprises an intranasal surface.

18. A microsphere comprising a polymeric carrier and an S-layer protein.

19. A microsphere according to claim 18 wherein said S-layer protein is coated on the surface of the microsphere.

20. A microsphere according to claim 18 or claim 19 which further comprises an agent that is capable of generating a protective immune response in an animal to which it is administered.

21. A microsphere according to claim 20 wherein one or more of said agents are linked to the S-layer protein.

22. A pharmaceutical composition comprising a microsphere according to any one of claims 19 to 22.

23. A pharmaceutical composition according to claim 22 wherein said composition is a vaccine, intended to produce a protective immune response against a bacterium, and said S-layer protein is derived from said bacterium.

24. The use of a chemical selected from

A) a polyamino acid,
B) a water soluble vitamin or vitamin derivative,
C) positively charged cationic pluronics,
D) a clathrate,
E) a complexing agent,
F) cetrimides;
G) an S-layer protein; or
H) Methyl-glucamine

as an immunostimulant, provided that in the case of A), the immunostimulant is applied to a mucosal surface, in the case of C, the compound is used in the absence of a polyacrylic acid.

25. The use of an adjuvant chemical selected from

A) a polyamino acid,
B) a water soluble vitamin or vitamin derivative,
C) positively charged cationic pluronics,
D) a clathrate,
E) a complexing agent,
F) cetrimides;
G) an S-layer protein; or
H) Methyl-glucamine

as an immunostimulant in the production of a vaccine for use in prophylactic or therapeutic treatment, provided that in the case of A), the immunostimulant is used in a vaccine which is applied to a mucosal surface, and in the case of C), the compound is used in the absence of a polyacrylic acid.